

## REMARKS

By way of the present amendment, claims 1-9, 11-14, and 20-25 are pending. Claims 1, 4, 9, 13, 14, and 20-22 have been amended without prejudice or disclaimer. New claims 23-25 have been added. No claims have been canceled. Certain of the amendments merely correct typographical errors, and do not narrow the claims in any regard. Support for the foregoing amendment can be found throughout the specification and claims as originally filed, *e.g.*, para [0024] of the published application. Entry of the amendment and reconsideration of the application as amended is respectfully requested.

### I. Claim Rejections - 35 U.S.C. § 102(b)

Claims 1-8 have been rejected as allegedly being anticipated by WO 03/039597 (Reference 10 from IDS dated 10/30/06 to QLT, Inc., hereinafter, “QLT”). This rejection is respectfully traversed for at least the reasons which follow.

The present claims relate to methods of treating acne vulgaris in a subject in need thereof, wherein method steps are repeated until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment. The cited prior art does not teach or suggest performing methods so as to achieve any stated degree of efficacy of treatment.

Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently. *MEHL/Biophile International Corp. v. Milgram*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). With particular reference to acne, QLT discloses “[t]he compositions of the present invention can be used for the treatment of acne. The present method comprises applying a composition of the present invention to a suitable target and activating the photosensitizing agent.” *QLT* at page 14. However, there is no teaching of a stated degree of reduction of acne lesions such that one of skill in the art would perform the disclosed methods in a manner (*e.g.*, repeating the steps of the disclosed methods) so as to achieve a stated reduction of acne lesions. For at least this reason, Applicants respectfully request withdrawal of the present rejection.

Nonetheless, in support of the rejection of dependent claim 8, the Examiner has asserted, “QLT, Inc. teaches administration of the same green porphyrin photosensitizers exposed to the same wavelength of energy for the same condition. The method wherein the steps are repeated until the total number of acne lesions has been reduced by 30% or more is considered to be

inherent in the method of QLT, Inc.” *Office Action issued January 27, 2011*, at page 3. Again, Applicants respectfully traverse.

“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

More particularly, in relying upon the doctrine of inherent anticipation, one must provide a basis in fact and/or technical reasoning to reasonably support a determination that the allegedly inherent characteristic necessarily will be present if the teachings of the prior art are followed. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The fact that a prior art article or process may possibly possess the characteristics of the claimed subject matter is not sufficient to destroy the novelty of the claimed subject matter. Inherency must be a necessary result, and not merely a possibility of the prior art. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).

Again, there is no teaching or suggestion in QLT of a stated degree of reduction of acne lesions such that one of skill in the art would perform the disclosed methods in a manner (*e.g.*, repeating the steps of the disclosed methods) so as to achieve a stated reduction of acne lesions. The mere teaching of the “administration of the same green porphyrin photosensitizers exposed to the same wavelength of energy for the same condition,” as alleged by the Examiner, would not necessarily teach or suggest the claimed method to achieve the stated reduction of acne lesions. As stated above, inherency requires a certainty that a property or characteristic exists. It “may not be established by probabilities or possibilities.” *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (internal quotations omitted).

For at least the above reasons, Applicants respectfully request that the rejection be withdrawn.

## II. Claim Rejection Under 35 U.S.C. § 103

Claims 13-14 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over QLT in view of Kalka *et al.* (hereinafter “Kalka”). This rejection is respectfully traversed for at least the reasons which follow.

The Examiner additionally rejects claims 13-14 over a combination of QLT and Kalka, alleging that Kalka teaches that “diode lasers are employed to produce red light in the range of 770 to 850 nm)” and “teach that photodynamic management of dermatologic conditions is simplified by the accessibility of the skin to light application and leaves the option to use any light device with the appropriate spectrum corresponding to the absorption maximum of the photosensitizing compound.” *Office Action mailed January 27, 2011*, at page 5. Applicants respectfully traverse.

While not agreeing with the Examiner’s characterization of the cited prior art, whatever else Kalka may disclose, it does nothing to remedy the deficiencies of QLT discussed above with regard to the failure to teach or suggest a stated degree of reduction of acne lesions such that one of skill in the art would perform the disclosed methods in a manner (*e.g.*, repeating the steps of the disclosed methods) so as to achieve a stated reduction of acne lesions. As such, the cited prior art, taken alone or together, does not teach or suggest the present claims. Withdrawal of this rejection is therefore respectfully requested.

Claims 1-9, 11, 12 and 20-22 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over QLT in view of Clement *et al.*, (US Pub. 2004/0166129, hereinafter “Clement”). This rejection is respectfully traversed for at least the reasons which follow.

The Examiner additionally rejects claims 1-9, 11, 12 and 20-22 over a combination of QLT and Clement, alleging that Clement teach “treatment of acne vulgaris comprising the use of retinoids.” Again, while not agreeing with the Examiner’s characterization of the cited prior art, whatever else Clement may disclose, it does nothing to remedy the deficiencies of QLT discussed above. As such, the cited prior art, taken alone or together, does not teach or suggest the present claims. Withdrawal of this rejection is therefore respectfully requested.

**III. New Claims**

New claims 23-25 recite additional details concerning reduction of the number of acne lesions according to the methods of the claims. As such, for at least the reasons discussed above, claims 23-25 are patentable over the art of record.

**CONCLUSION**

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (303) 863-2303 should any additional information be necessary for allowance.

Respectfully submitted,

/Milan M. Vinnola/

David R. Marsh (Reg. No. 41,408)

Milan M. Vinnola (Reg. No. 45,979)

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ARNOLD & PORTER LLP

Attn: IP Docketing

555 12<sup>th</sup> Street, N.W.

Washington, D.C. 20004

(202) 942-5000 telephone

(202) 942-5999 facsimile